

CAB REGISTRATION NUMBER: **MDA/CAB-016**
VALIDITY: **22/11/2024 - 21/11/2027**

GENUINE DIAMOND SDN. BHD.

NO. 43B JALAN BP 7/12
BANDAR BUKIT PUCHONG
47120 PUCHONG
SELANGOR DARUL EHSAN
TEL: +603-8069 1111
FAX: +603-8069 1133



PERSON RESPONSIBLE:

PN. NUR ROSMARINIE BINTI BAHAROM
[\[info@genuinediamond.com.my\]](mailto:info@genuinediamond.com.my)

CONTACT PERSON:

PN. NUR ROSMARINIE BINTI BAHAROM
[\[info@genuinediamond.com.my\]](mailto:info@genuinediamond.com.my)

SCOPE OF REGISTRATION

Conformity Assessment of Quality Management System (QMS) and Post-Market Surveillance System (PMSS)

1	ISO 13485	Quality Management System for Medical Devices – Requirements for Regulatory Purpose
2	GDPMD	Good Distribution Practice for Medical Devices

Conformity Assessment of Technical Documentation

3	MD 0101	Non-active devices for anesthesia, emergency and intensive care
4	MD 0102	Non-active devices for injection, infusion, transfusion and dialysis
5	MD 0104	Non-active medical devices with measuring function
6	MD 0106	Non-active instruments
7	MD 0107	Contraceptive medical devices
8	MD 0108	Non-active medical devices for disinfecting, cleaning, rinsing
9	MD 0301	Bandages and wound dressings
10	MD 0302	Suture material and clamps
11	MD 0303	Other medical devices for wound care
12	**MD 1101	Devices for extra-corporal circulation, infusion and haemopheresis
13	MD 1102	Respiratory devices, including hyperbaric chambers for oxygen therapy, inhalation anesthesia
14	MD 1103	Devices for stimulation or inhibition
15	MD 1104	Active surgical devices
16	MD 1105	Active ophthalmologic devices
17	MD 1106	Active dental devices
18	MD 1107	Active devices for disinfection and sterilization
19	MD 1109	Active devices for patient positioning and transport
20	MD 1201	Imaging devices utilizing ionizing radiation
21	MD 1202	Imaging devices utilizing non-ionizing radiation
22	MD 1301	Monitoring devices of non-vital physiological parameters
23	MD 1302	Monitoring devices of vital physiological parameters
24	MD 1401	Devices utilizing ionizing radiation
25	MD 1402	Devices utilizing non-ionizing radiation
26	IVD 0101	AB0 system
27	IVD 0102	Rhesus (C, c, D, E, e)
28	IVD 0103	Anti-Kell

29	IVD 0201	HIV infection (HIV 1 and 2)
30	IVD 0202	HTLV I and II
31	IVD 0203	Hepatitis B, C and D
32	IVD 0301	Anti-Duffy and anti-Kidd
33	IVD 0302	Irregular anti-erythrocyte antibodies
34	IVD 0303	Congenital infections: rubella, toxoplasmosis
35	IVD 0305	Human infections: cytomegalovirus, chlamydia
36	IVD 0307	Tumoral marker: PSA
37	IVD 0401	Clinical chemistry
38	IVD 0402	Haematology
39	IVD 0403	Immunology
40	IVD 0404	Molecular biology
41	IVD 0405	Pregnancy and ovulation
42	IVD 0406	Specimen receptacles
43	MDA 7001	Medical devices incorporating medicinal substances, according to Directive 2003/32/EC
44	MDS 7002	Medical devices utilizing tissues of animal origin, including /Directive 2003/32/EC
45	MDS 7206	IVDs in sterile condition
46	MDS 7210	IVDs utilizing material of human origin

** means approval only for conformity assessment on infusion medical devices.

Conformity Assessment by Way of Verification		
47	VERIFICATION	Conformity Assessment by Way of Verification